

REMARKS

Claims 48-63 were pending before this Response. By the present communication, claims 50 and 51 have been cancelled, and no claims have been added or amended. Accordingly, claims 48, 49 and 52-63 are currently pending. Applicant respectfully requests entry and consideration of this amendment.

The Declaration

The Office Action indicates that the Declaration filed herein fails to meet the requirement of 35 C.F.R. 1.67(a) in failing to identify the application by number and filing date and by containing allegedly improper priority information. A fully executed Declaration overcoming the alleged deficiencies was submitted with the Response mailed on September 23, 2003. Applicants respectfully submit that the new Declaration meets all requirements under 35 C.F.R. 1.67(a). Therefore, reconsideration and withdrawal of the requirement for a new declaration are respectfully requested.

The Objection to the Claims

The Office Action indicates that claims 50 and 51 are objected to under 37 CFR § 1.75(d)(1) as being in improper form because the claims state an improper Markush group. Claims 50 and 51 have been cancelled by amendment in this Response. Therefore, Applicants submit that the grounds for the rejection are rendered moot. Reconsideration and withdrawal of the objection to the claims under 37 CFR § 1.75(d)(1) are respectfully requested.

The Rejection Under 35 U.S.C. § 112, First Paragraph

Applicant respectfully traverses the rejection of claims 48-63 under 35 U.S.C. § 112, first paragraph, as containing subject matter allegedly not described in the specification in such a way as to convey that the Applicant was in possession of the claimed subject matter at the filing of the application. Applicant disagrees with the Examiner's assertion that "the specification fails to

describe any specific biomolecule or bioactivity by any structure *or properties*" (Office Action, page 3; emphasis added).

The claims have previously been amended to recite "a protein having an activity of interest." Throughout the Specification, enzymes are used as an illustration of how the screening of a gene expression library can be used to obtain proteins "having an activity of interest" by detecting the presence of the activity of interest produced by one or more constructs in the gene library.

Example 2 of the Specification provides a "representative example" of the procedure used for screening an expression library for enzymatic activity in "Tiers", proceeding from hydrolase in Tier 1 to amide, ester and acetal in Tier 2, to differences between individual substrates covalently attached to the functionality of Tier 2 in Tier 3, and possible enantiomeric products that an enzyme may produce from a substrate in Tier 4. Table 1 of the Specification provides substrates that can be used to screen for the various enzyme activity classes (types of amide hydrolase) of Tier 3 that are shown in Figure 1 of the Specification (i.e., terminal amidase, cyclic amidase, acylase and peptidase). Where the recombinant clone from the library is identified in Tier 2 as providing an ester, the Specification in Figures 2 and 3, shows the various substrates to be used for testing for various functionalities of the ester identified in Tier 2 by reference to the compounds whose structures are shown in Tables 2, 3 and 4. Further, the compounds whose structures are shown in Table 5 may be used for testing to provide a protein having any of the Tier 3 activities shown in Figure 3. Thus, Applicant respectfully submits that those of skill in the art would have an understanding upon reading the Specification that the Applicant was in possession of the concept of using the disclosed method for the purpose of obtaining a protein, such as an enzyme, that has an activity of interest. Furthermore, Applicant submits those of skill in the art would understand that the Applicant conceived of the method as a general method that is not restricted to providing a single protein or enzyme having an activity of interest.

Thus, Applicant submits that those of skill in the art, upon reading the Specification, would understand that the Applicant was in possession of the invention, as defined by claims 48-

63, at the filing of the application. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

The Rejection Under 35 U.S.C. § 102(b)

Applicant respectfully traverses the rejection of claims 48-58 for allegedly being anticipated by “the commercial availability of numerous natural products . . .” (Office Action, page 4). Applicant submits that the invention proteins having an activity of interest, as defined by amended claim 48, distinguish over the numerous natural products that are commercially available by the method of their obtaining, which method comprises:

- a) culturing a gene expression library comprising a pool of expression constructs, each expression construct comprising one cDNA or genomic DNA fragment, wherein the cDNA or genomic DNA fragments in the pool of expression constructs are derived from a plurality of species of donor organisms, and wherein the cDNA or genomic DNA fragments are each operably-associated with one or more regulatory regions that drives expression of genes encoded by the cDNA or genomic DNA fragments in an appropriate host organism; and
- b) screening the expression constructs to identify one or more expression construct containing a vector that produces a protein activity of interest;
- c) removing the cDNA or genomic DNA fragments from the one or more expression construct identified in b); and
- d) expressing the DNA encoding the protein of interest, thereby obtaining the protein having an activity of interest.

Applicant disagrees with the Examiner’s assertion:

The patentability of a product of a method resides in the product itself and not the method by which it is made or identified.

(Office Action, page 3). The Examiner relies upon passages from *Atlantic Thermoplastics Co. v. Faytex Corp.* (especially, pages 1387, second paragraph through the end of the second paragraph on page 1492) in support of this position. However, the Examiner’s interpretation of the significance of *Atlantic Thermoplastics* is misplaced. The Federal Circuit had earlier held in

Scripps Clinic & Research Fund. v. Genentech, Inc. (18 USPQ2d 1001 (Fed. Cir. 1991) that a product is new if the method of obtaining it is new. Because the Federal Circuit sits in panels of three judges, if two decisions of the Federal Circuit are in conflict, *the earlier decision is the controlling precedent*. A later panel of only three judges cannot overrule a prior decision of the court, as in *Atlantic Thermoplastics*. The Federal Circuit must sit *en banc* in order to overrule a prior decision of the court (*Johnston v IVAC Corp.*, 885 F.2d 1574, 1579 (Fed. Cir. 1989)). A Request for Rehearing En Banc of the *Atlantic Thermoplastics* case was denied Aug. 14, 1992. Therefore, at present the controlling precedent in the Federal Circuit, as was noted for example in *Columbia University v. Roche Diagnostics GmbH*, 57 USPQ2D 1925 (D. Mass. 2000), is that of court in the *Scripps Clinic* case, which held that where the process by which the protein is obtained is new, the protein obtained is new.

In the present case, the process by which the protein is obtained is “new”. The process is the subject matter of U.S. Patent No. 6,528,249, of which Applicant is the named inventor. Therefore, under the controlling precedent of *Scripps Clinic*, the method of obtaining a protein having an activity of interest is both “novel and unobvious”. Accordingly, Applicant submits that the claims of the present invention directed toward a protein obtained by the patented method are also novel and unobvious.

Based on the remarks above and the recent CAFC decisions on product by process cases, Applicant submits that anticipation of the invention proteins, as defined by claims 48-63, is not established by commercial availability of numerous natural products, as asserted by the Examiner. Applicant, therefore, requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

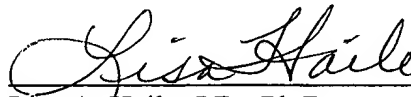
In re Application of:
Jay M. Short
Application No.: 09/421,629
Filed: October 19, 1999
Page 9

PATENT
Attorney Docket No.: DIVER1260-3

In view of the above amendments and remarks, Applicant submits that all objections and rejections are now overcome, and passage of the claims to allowance is respectfully requested. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: April 23, 2004



Lisa A. Haile, J.D., Ph.D.
Registration No.: 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
USPTO CUSTOMER NO. 28213